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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/945,425	10/21/1997	CHRISTER CEDERBERG	1103326-282	2696

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EXAMINER
DESAI, RITA J

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	08/945,425	CEDERBERG ET AL.	
	Examiner	Art Unit	
	RITA J. DESAI	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,18,19,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,18,19,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

The applicants have not amended the claims drawn to just the elected group of the restriction in paper #5.

Applicants are required to cancel the non-elected subject matter.

The rejection of claims 1-11, 15,16, 18-19, 26 and 27 under 35 USC 103 over US 5330982 Tyers still stands.

The reference clearly teaches the omneprezole as an H+ K+ ATPase inhibitors.

The reference also clearly teaches the doses 110-500mg per day. 5-250 mg, 5-100, 5-60mg ,or 10-60 mg per day. The reference also teaches that these can be administered *1* to 4 times a day.

See Column 8 lines 57-68, column 9 lines 1-19.

The applicants claims are also drawn to a method of treating the gastric acid secretion, which is the same as that of the prior art.

The doses used is also the same. Even though the prior art teaches the composition it still does teach the omneprezole

In re Best, Bolton and Shaw CCPA 195 USPQ 430.

"*Mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; Patent Office can require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior*

art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics."

Applicants blood plasma profile is more of a discovery of the properties than a patentable distinction over the prior art.

Claim Rejections - 35 USC § 102

The rejection of claims 1-11, 15, 16, 18-19, 26 and 27 under 35 USC 102 over WO 96/01624 has been withdrawn since the overall patent is drawn to different tablet and coating but in view of further arguments please see new 103 rejection.

The rejection of claims 1-11, 15, 16, 18-19, 26 and 27 under 35 USC 102 over Martindale still stands. Martindale clearly discloses , even according to applicants arguments , Martindale does teach ***a single dose since the duration of action with regard to the inhibition of acid secretion is much longer.*** Hence at the time the invention was made it was known that a higher dose would have a longer duration of action.

Again Applicants blood plasma profile is more of a discovery of the properties than a patentable distinction over the prior art, since the actual treatment is the same.

In re Best, Bolton and Shaw CCPA 195 USPQ 430.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 15, 16, 18-19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/01624 . and US 5330982 Tyers.

Applicants invention is drawn to a method of treating gastric acid secretion, using omneprazole or its derivatives, by improving the blood plasma profile.

This is done by giving a single large dose a day, or repeated doses at small intervals.

(See specifications , Detailed description lines 27-30 which clearly states repeated regimen or dosage form which provide an extended blood plasma profile recovered pumps as well as unhibited pumps, not previously active will react"

Scope and Content of Prior Art MPEP 2141.01

The prior art WO 96/01624 teaches the same compound with the same doses, to treat the same gastric acid secretion. See the background of the invention pages 1- 5.

The activity is taught on lines 10-15 page 5.

On page 18 under Use of preparation it clearly teaches that it can be administered one to several times a day, and also that the daily dose is within the range 1-1000mg.

Tyers '982 further teaches the different doses. See doses 110-500mg per day. 5-250 mg, 5-100, 5-60 mg ,or 10-60 mg per day. The reference also teaches that these can be administered *1* to 4 times a day.

See Column 8 lines 57-68, column 9 lines 1-19.

Difference Between the Prior Art and the Claims MPEP 2141.02

The prior art WO 96/01624 over all teaches the coating of the tablets and the different formulation in a broad range of dosage of 1-1000mg daily.

Prima Facie Obviousness Rational and Motivation MPEP 2142-2143

Even though the WO '624 reference teaches that it can be taken in a daily dose of 1-1000 mg daily Tyler teaches all the various dosages and also that it can be taken 1-4 times a day. Thus it would have been Prima Facie Obvious for one skill in the art at the time the invention was made to take a higher dose or a repeated regimen or even a dosage preparation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 18, 26 and 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicants are claiming an improvement of treating gastric acid secretion , but the claims do not clearly explain how. The applicants claim of increasing the blood plasma profile does not have any previous standard or a comparison to indicate what the profile is being changed to. The figure 1 just shows a comparison of 20 and 40 mg dose which are taken at different rates.

Conclusion

The claims are hence not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

R.D.
October 2, 2002